

REMARKS

Claims 1-4, 11-13, 21, 28, 32, 34, 37, 40, 42, 43, 47, 48, 83, 86, 100 and 101 are pending in this application. Claims 5-10, 14-20, 22-31, 33, 35, 36, 41, 44-46, 49-82, 85 and 87-99 have been withdrawn by the Examiner as being drawn to a non-elected invention.

Applicants wish to clarify whether claim 84 was examined with the presently pending claims. Claim 84 was not discussed on the Office Action Summary Sheet or at page 3 as having been examined or withdrawn.

Applicants respectfully disagree with the statements at pages 2-3 of the Office Action that the elections were made without traverse. Applicants' response clearly stated that the elections were made with traverse and that there was no undue burden on the Examiner to search the subject matter of Groups I and II.

The class and subclasses listed for search are identical. According to M.P.E.P. Sec. 803 "[I]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions". Separate classification, separate status in the art or different field of search has not been shown and therefore the prima facie showing as a basis for restriction/election has not been met. Therefore, the supposed errors (no undue burden to search) were distinctly and specifically pointed out and each restriction/election response should be treated as having been made with traverse.

At pages 3-5 of the Office Action, claims 21 and 32 have been rejected under 35 U.S.C. § 112, first paragraph because of lack of enablement. For brevity, reference is made to pages 3-5 of the Office Action for the complete reasons for rejection.

While Applicants respectfully disagree with and traverse this rejection, claims 21 and 32 have been amended to include a list of cardiovascular agents to expedite allowance of the present application, without prejudice to filing of one or more divisional patent applications directed to the canceled subject matter thereof.

Accordingly, Applicants respectfully request that the rejection of claims 21 and 32 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

At pages 5-6 of the Office Action, claims 34, 47, 84 and 101 have been rejected under 35 U.S.C. § 112, first paragraph because of lack of enablement. For brevity, reference is made to pages 5-6 of the Office Action for the complete reasons for rejection.

While Applicants respectfully disagree with and traverse this rejection, claims 34, 47, 84 and 101 have been amended to remove the phrase "or prevention" to expedite allowance of the present application, without prejudice to filing of one or more divisional patent applications directed to the canceled subject matter thereof.

Accordingly, Applicants respectfully request that the rejection of claims 34, 47, 84 and 101 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

At pages 6-8 of the Office Action, claims 1-4, 11-13, 21, 28, 32, 34, 37-40, 42, 43, 47-48, 83, 86 and 100-101 have been rejected under 35 U.S.C. §103(a) as obvious over US 5,846,966 ("Rosenblum et al.") and The Medical Letter on Drugs and Therapeutics (1998) 40:1030: 68-69 ("Medical Letter"). Claims 21 and 32 were rejected under 35 U.S.C. §103(a) as obvious over Rosenblum et al. and the Medical Letter, further in view of Basic & Clinical Pharma., 6th Ed. (1995) 529 ("Katzung").

For brevity, the reasons for rejection are not repeated herein but reference is made to the outstanding Office Action.

Applicants respectfully traverse these rejections and request that the rejections be reconsidered and withdrawn.

When making a rejection under 35 U.S.C. § 103, the Examiner has the burden of establishing a prima facie case of obviousness. In re Fritch, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The Examiner can satisfy this burden only by showing an objective teaching in the prior art, or knowledge generally available to one of ordinary skill in the art, which would lead an individual to combine the relevant teachings of the references [and/or the knowledge] in the manner suggested by the Examiner. Id.; In re Fine, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

The mere fact that the prior art could be modified does not make the modification obvious unless the prior art suggests the desirability of the modification. In re Fritch, 23 U.S.P.Q.2d at 1784; In re Laskowski, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989); In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984).

"It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious....[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." In re Fritch, 23 U.S.P.Q.2d at 1784 (quoting In re Fine, 5 U.S.P.Q.2d at 1600).

"The ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the

persuasiveness of any arguments and any secondary evidence." Manual of Patent Examining Procedure, (Rev. 1, Feb. 2003) § 716.01(d) and In re Oetiker, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

It is respectfully submitted that the combination of the references cited as rendering the claimed invention obvious is improper because there is no suggestion in the cited references to combine the claimed components of sterol absorption inhibitor (such as that of Formula (II) (e.g., ezetimibe)) and PPAR activator (such as fenofibrate).

Neither Rosenblum et al. nor Medical Letter provides motivation for substituting a PPAR activator for the statin used in combination with ezetimibe described in Rosenblum et al. There is no guidance provided by Rosenblum et al. nor Medical Letter to pick and choose among numerous cholesterol treatments to select the particularly claimed combination of sterol absorption inhibitor (such as that of Formula (II) (e.g., ezetimibe)) and PPAR activator (such as fenofibrate).

With respect to claims 21 and 32, neither Rosenblum et al., Medical Letter nor Katzung, taken alone or together as suggested in the Office Action, provides any motivation for a triple combination treatment of sterol absorption inhibitor (such as that of Formula (II) (e.g., ezetimibe)), PPAR activator (such as fenofibrate) and niacin. These references provide no guidance or motivation as to the desirability for such as combination or selecting the particular components of the combination.

Because of the difference of the way that each component of the presently claimed combination acts, it is respectfully submitted that the rejection is based upon an improper combination of references.

Accordingly, reconsideration and withdrawal of the §103(a) rejections is respectfully requested.

Applicants respectfully request that the Examiner return an initialed PTO-1449 form for the Information Disclosure Statement submitted herewith and each of the Information Disclosure Statements submitted on April 16, 2004 and May 5, 2003, indicating that the Examiner has considered each of the references cited therein.

In view of the foregoing remarks, it is respectfully submitted that all of the pending claims in the present application comply with the requirements of 35 U.S.C. § 112 and are distinguishable from the cited prior art. Accordingly, reconsideration

and withdrawal of the rejection and an early Notice of Allowance are respectfully requested.

Respectfully submitted,

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